AMENDMENT

In the Claims

Please cancel claims 14-20.

REMARKS

The 35 U.S.C. §102 Rejection

Claims 1-7 and 9-12 were rejected under 35 U.S.C. §102(b) as being anticipated by **Herndon** et al. The rejection is respectfully traversed.

Claims 1 and 9 have been amended previously to recite methods of treating an individual having a severe burn, wherein the treatment with beta-adrenergic antagonist or propranolol improves skeletal muscle protein kinetics in the individual as compared to individual without the treatment. The present invention discloses "β blockade improved skeletal muscle protein kinetics. Propranolol administration improved muscle protein net balance from baseline (p=0.005) and as compared with non-treated controls (p=0.001)

(Figure 2)" (page 23, lines 9-13). Using stable isotope methodology and serial body composition scanning, the present invention shows for the first time that β blockade with propranolol diminishes skeletal muscle protein wasting seen after severe burn (page 28, Discussion; Figure 2 and Table 3). Out of twenty-five severely burned children studied, thirteen children were safely given propranolol and experienced a decrease in resting energy expenditure. Twelve children had improved net muscle protein balance. With long-term β-blockade, this result translated into greater lean body mass. Applicant submits that **Herndon** et al. do not teach or suggest methods of treatment that can improve skeletal muscle protein kinetics in severe burn patients as claimed herein.

The Examiner contends that **Herndon** et al. teach burn treatment using beta adrenergic blockers such as propranolol. However, **Herndon** et al. only teach "nonselective beta-adrenergic receptor blockade with propranolol can be therapeutic in severely burned children and adults by reducing heart rate and myocardial workload" (page 1301, left column). **Herndon** et al. do not teach or suggest treatment with propranolol would improve skeletal muscle protein kinetics in severe burn patients as claimed herein.

Herndon et al. as a whole do not teach or suggest treatment with propranolol can improve skeletal muscle protein kinetics in severe burn patients. Instead, **Herndon** et al. teach that treatment with propranolol had no effect on muscle protein metabolism in burned patients. **Herndon** et al. conclude that

> "in the present study, we failed to document an effect of propranolol and metoprolol on protein kinetics, although an earlier study indicted an increase in urea production with propranolol. .....in the present study, we used two independent approaches of assessing net protein breakdown. The fact that neither of these techniques revealed any significant effect of either agent on protein kinetics indicates that the effect is of minimal clinical concern. In summary, selective β1-adrenergic and nonselective adrenergic receptor blocking agents can significantly reduce heart rate and myocardial oxygen consumption in hypermetabolic burned patients without adversely affecting protein kinetics." (page 1304, left column, second and third paragraphs).

Therefore, based on the teaching of no effect on protein kinetics disclosed in **Herndon** et al., the instant finding of improved skeletal muscle protein kinetics in individual treated with beta-adrenergic antagonist or propranolol is an unexpected result.

In response to Applicant's argument as discussed above, the Examiner did not address nor rebut the teaching of **Herndon** et al. as cited above. Rather, the Examiner merely states without any scientific support that "skeletal muscle kinetic improvement is naturally occurring when beta adrenergic antagonists are administered to the patient with burns, and thus it is considered to be inherent feature."

Applicant submits that the Examiner's assertion is illogical in view of the teaching of **Herndon** et al. **Herndon** et al. clearly teach that treatment with propranolol had no effect, let alone improvement, on muscle protein metabolism in burned patients. Obviously, the Examiner's conclusion of improved skeletal muscle kinetic by propranolol has no basis in and directly contradicts with the teaching of **Herndon** et al.

The Examiner concludes that the cited reference meet all the critical elements required by the claims, and all the claimed subject matter is anticipated by the cited reference. Applicant respectfully disagrees. Applicant submits that **Herndon** et al. teach treatment with propranolol had no effect on muscle protein metabolism in burned patients. **Herndon** et al. do not teach or suggest treatment with propranolol can improve skeletal muscle protein kinetics in severe burn patients as claimed herein. Therefore, **Herndon** et al. do not meet all the critical elements required by the claims of the present invention.

In view of the above remarks, **Herndon** et al. did not teach or suggest each and every aspect of the instant invention. Instead, **Herndon** et al. teach away from the present invention. Hence, **Herndon** et al. did not anticipate claims 1 and 9 of the instant application. Accordingly, Applicant respectfully requests that the rejection of claims 1-7 and 9-12 under 35 U.S.C. §102(b) be withdrawn.

This is intended to be a complete response to the Final Office Action mailed October 8, 2002. If any issues remain

outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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